Microbiology for Non-Microbiologists

Understand the true meaning of microbiological findings

26 - 27 February 2014, Berlin, Germany

SPEAKERS:

Colin Booth
Oxoid, UK

Arjan Langen
MSD, The Netherlands

Elaine Nichols
Oxoid, UK

LEARNING GOALS:

- Acquire a Basic Knowledge in Microbiology
- Develop an Understanding for the Meaning of Microbiology for the Quality of Medicinal Products
- Get familiar with typical microbiological Tests in the Pharmaceutical Industry
- Learn to interpret microbiological Data correctly

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager"

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Objectives

It is the aim of this course to familiarise responsible personnel from production, quality assurance and engineering with microbiological questions. The participants **learn how to interpret microbiological data** and which consequences these have for the production.

Background

The quality of drugs and the quality assurance during production are above all determined by their microbiological characteristics. The microbiological requirements on drugs are laid down in various regulations. When an authority inspects a company, it will focus its attention on these and on the requirements made on hygiene.

In their daily work, the responsible personnel in the production units has to understand microbiological results and evaluate their significance for further decisions. However, in practice **many microbiological results are misinterpreted** and thus often the wrong conclusions are drawn from them. When asked for the most frequent misinterpretations of microbiological results, pharmaceutical microbiologists gave the following answers.

- The difference between bioburden and sterility testing (are they the same?)
- The use of disinfectants guarantees the sterility of the object, surface, culture treated.
- The distribution of microorganisms in a sample or on a surface is uniform.
- Motile microorganisms can swim hundreds of meters in an hour causing contamination problems in remote parts of the facility.
- How can different media formulations give different results?
- Microbial tests described in the Pharmacopoeias can always be validated, no matter what the matrix is, how aggressive it is, e.g. NaOH, how high the concentrations of antibiotics are etc.
- Identification results are absolute and unequivocal, especially when computer-generated.
- Underestimating the importance of cleaning prior to disinfection.
- Environmental monitoring results provide an accurate risk assessment during production.
- How can clean room surfaces not be heavily contaminated when the air counts are out of specification?
- How can endotoxins be present when the bioburden is nil?
- How can the titre of a virus reference standard change according to the detection cell line used?
- WFI is sterile.
- Filters are absolute.
- UV light disinfects and is capable of sterilising surfaces and water.

This listing appears to cover all aspects of microbiology from the interpretation of straightforward issues concerning environmental monitoring, bioburden results and identifications – through to the more complex issues surrounding virology results for the biologics/biotech people.

The misinterpretation of microbiological results often gives rise to the following misunderstandings:

- Huge environmental monitoring programmes (more is better).
- Rejection of batches due to minor out-of- specification results.
- Delayed registration objectives and to attend appeal hearings.
- Numerous contamination incidents due to the application of inappropriate solutions to problems.
- Senseless promises made to regulatory authorities without scientific rationale based on the concept of quality.

Target Group

This course is designed for responsible personnel from **production, quality assurance, regulatory affairs and engineering** that has to make judgements, release products and take actions on the basis of the microbiological data supplied.

Programme

The Characteristics of Microorganisms

- Fungi
- Bacteria
- Mycoplasma
- Viruses
- Cellular organisation, function
- Products; toxins, endotoxins, antibiotics, enzymes

Microbial Growth

- How it occurs
- What is required for growth?
- Growth kinetics – laboratory culture versus nature
- Effect of stress factors on growth

Microbial Identification Techniques

- What is the significance of a name?
- Distribution of microorganisms in nature, raw materials and water
- Distribution of microorganisms in pharmaceutical facilities

Detection Methods and Their Limitations

- What can be detected by:
  - The sterility test
  - The bioburden test in its various forms. Membrane filtration, pour plate, spread plate,MPN
  - The test for specified organisms
  - The endotoxin test
- Limits of detection and factors effecting limits of detection

Validation of Microbial Test Methods
- Basic principles of validating a microbial test system
- What approaches can you take when a microbial assay test cannot be validated?

Cleaning, Sanitation, Disinfection
- Why cleaning before disinfection?
- The difference between cleaning and disinfection
- Disinfectants and their efficacy
- Methods of disinfection
- Disinfection validation

Environmental Monitoring
- Sampling techniques
  - air sampling
  - surfaces
  - settle plates
- Technical limitations and interpretation of results
- Is there a relationship between high results and contaminated product?

How To Handle Microbiological OOS Results?
- Typical Out-Of-Specification results
  - Sterility testing
  - Bioburden
  - Endotoxin testing
  - Cleanroom monitoring
- Investigation of Causal Connection
  - Laboratory failure investigations
  - Sampling/process/production failure investigation
  - Type of microorganisms
  - Deviations/incidents/assessment
  - Deviation/investigation report
- Retesting/Reanalysis/Resampling
  - Definitions
  - Calculation of mean values
  - Rejection/Release

Sterilisation Methods
- Principles and kinetics of sterilisation
- Selection of sterilisation method
- Types of sterilisation methods
- Validation of the sterilisation process

Social Event

On the evening of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Workshops
The objective of these workshop sessions is to give the participants some hands on experience with the fundamentals of microbial techniques and the difficulties associated with interpretation. They will also provide the chance to discuss common problems in an informal atmosphere.

Workshop 1:
Endotoxin testing (LAL).
Participants can take part in an endotoxin test. The Session will illustrate the fragility of the system and highlight interpretation problems.

Workshop 2:
Trouble shooting in the microbiological laboratory.
The focus will be on those problems that occur frequently in microbiological quality control. Practicable solution to these challenges will be discussed in small groups.

Speakers

Colin Booth, *Oxoid, UK*
Colin Booth was the manager of pharmaceutical microbiology of Glaxo Wellcome Research and Development based in the UK where he was responsible for all the microbiology associated with the development of all Glaxo Wellcome new products. In 2002 he joined Oxoid Limited where he is now Vice President Science and Technology. Colin is an ECA Advisory Board Member covering the field of Development Microbiology.

Arjan Langen, *MSD, The Netherlands*
Arjan Langen was manager of Microbiological Quality Control and Quality Assurance officer at Intervet International in The Netherlands before he joined Nobilon International. At Nobilon he was appointed Quality Assurance Manager, responsible for the cGMP-approval of the new multi-purpose vaccine production facility in Boxmeer , The Netherlands. In 2008 Arjan became Director Compliance at DSM Pharmaceutical products and in 2009 he founded his own company for training and consulting in the field of pharmaceutical microbiology. In 2011 he became Pharmaceutical Specialist at MSD in The Netherlands, being responsible for sterile manufacturing of new products in Oss. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

Elaine Nichols, *Oxoid, UK*
Elaine Nichols is Quality Manager at Oxoid Ltd Thermo Fisher Scientific. She is responsible for Quality Assurance, Regulatory Affairs and Compliance. Her background is as a microbiologist in Quality Control, manager of Product Performance and R&D projects manager.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
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Fax +49 (0) 62 21/84 44 34

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Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **PO Number if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

Date

Wednesday, 26 February 2014, 09.30 h – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 27 February 2014, 09.00 h – 15.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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Fees

ECA-Members: € 1,490.– per delegate + VAT
APIC Members: € 1,590,- per delegate + VAT
(does not include ECA Membership)
Non-ECA Members: € 1,690.– per delegate + VAT
EU GMP Inspectorates: € 845.– per delegate + VAT
Including: Conference documentation, lunch on both days, all refreshments, social event on the first day. The registration fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form with all further information when you have registered for the course. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.

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